DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2367n

NOV 30 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Gordon Paul Smith
President
Garavanta (Canada) Ltd.
P.O. Box 1769
Blaine, Washington 98231-1769

Dear Mr. Smith:

During an inspection of your firm (Garaventa) located in Surrey, B.C., Canada, on July 28-29, 1998, our investigator determined that your firm imports, repackages, and relabels; i.e., manufactures, the "Stair – Trac," "Stair-Porter," and the "Evacu-Trac." These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your firm imports these devices into Canada from Sunwa Ltd. (Sunwa), Sayama, Saitama 350-1325, Japan. Sunwa manufactures the three devices. Specifically, your firm receives the finished devices, inspects the shipments, adjusts the devices, final inspects the devices, applies labeling to the devices, packages the devices, and then ships these devices to customers in the United States. Our investigator inspected Sunwa on August 31-September 2, 1998, and this letter is also based on information obtained during that inspection. Sunwa provided us with a written response on September 30, 1998, concerning the inspection of its firm, which is referenced below.

The above–stated inspections of your firm and Sunwa revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for their manufacture, packaging, storage, or installation are not in conformity with the Quality System regulation (QS regulation), as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

Garaventa Inspection

1. Failure to establish and maintain procedures for reviewing and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example:

   a. The complaint procedure contained in the Corrective and Preventive Action 4.14 procedure does not establish responsibility between Garavanta and Sunwa Ltd. in the following areas:

      (1) Reviewing and evaluating the significance of complaints;

      (2) Who is responsible for conducting and documenting investigations or deciding not to conduct investigations;

      (3) How and when complaints will be communicated to the manufacturer; and

      (4) How the results of an investigation will be communicated back to Garaventa.

   b. There is inadequate documentation to show when complaints are forwarded and discussed with the manufacturer; and

c. Garaventa only collects the initial complaint information, and gives this to Sunwa for review and evaluation.

With respect to item 1 a (1)-(4) above, during the inspection, your firm stated it would work with Sunwa to establish responsibility, and would create a complaint procedure, which will document how "Trac" products will be processed. The adequacy of the response cannot be evaluated until we receive the procedure. The procedure will have to show that Garaventa bears all the responsibility.

With respect to item 1 b above, your firm stated during the inspection that it will establish responsibility, update the complaint procedures, forward all complaints immediately to Sunwa, and keep all documentation. The adequacy of the response cannot be evaluated until we receive the updated procedures. However, it should be noted that Garaventa is ultimately responsible for the entire corrective and preventive action requirements, to include all the requirements of nonconforming product. Garaventa needs to have procedures that demonstrate how Garaventa is ensuring compliance with all of these requirements.

2. Failure to review and evaluate all complaints to determine whether an investigation is necessary, and failure to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its specifications, unless such investigation has already been performed for a similar complaint and another investigation is not necessary, as required by 21 CFR 820.198(b) and 21 CFR 820.198(c), respectively. For example, Garaventa only collects the initial complaint information and gives this to Sunwa for review and evaluation to determine whether an investigation is necessary. However, the inspection of Sunwa showed that Sunwa was not adequately utilizing the information forwarded by Garaventa.

   Garaventa is ultimately responsible for ensuring compliance with these requirements.

3. Failure to analyze complaints to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1). For example, Garaventa failed to document trend analysis of complaints.

   During the inspection, your firm stated that complaints will be trended. Your response is not adequate. Garaventa will have to provide a documented procedure to assure this occurs, to comply with 21 CFR 820.100(a)(1). Garaventa is ultimately responsible for ensuring compliance with this requirement.

4. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). For example, Garaventa's operations include inspecting shipments, adjusting the device, and final inspection, yet:

   a. Garaventa has not ensured that the Stair-Trac specifications in the Garaventa Stair-Trac Inspection and Assembly Instructions of an upstairs speed of 6.5 m/min and downstairs speed of 7.7 m/min are being met. These specifications were not supported by test data collected during the inspection of Sunwa, and Sunwa test data dated September 19, 1998, determined that the actual specifications are an upstairs speed of [redacted] m/min and a downstairs speed of [redacted] m/min; and

b. Garaventa has not ensured that the Stair-Porter specifications in the Garaventa Stair-Porter Inspection and Assembly Instructions of an upstairs speed of 6m/min and downstairs speed of 8.6 m/min are being met. These specifications were not supported by test data collected during the inspection of Sunwa, and Sunwa test data dated September 19, 1998, determined that the actual specifications are an upstairs speed of [redacted] m/min and a downstairs speed of [redacted] m/min.

Garaventa is ultimately responsible for ensuring compliance with this requirement. For example, Sunwa could certify this, and Garaventa would have to periodically confirm this through, for example, third-party testing. Garaventa needs to have procedures to demonstrate how it is ensuring compliance with these requirements.

5. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product conforms to specified requirements, as required by 21 CFR 820.50. For example, see 4 a and b above.

   Garaventa is ultimately responsible for ensuring compliance with this requirement.

6. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). For example, see 4 a and b above. There is no information that Garaventa controlled these products that did not conform to specified requirements.

   Garaventa is ultimately responsible for ensuring compliance with this requirement.

Sunwa Ltd. Inspection

7. Failure to analyze complaints and service records to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1). For example, Sunwa failed to have analysis or trending type information for complaints and service records.

   Sunwa's September 30, 1998, response appears to be adequate.

8. Failure to analyze service reports with appropriate statistical methodology in accordance with 21 CFR 820.100, as required by 21 CFR 820.200(b). For example, three of six service reports audited for the Stair-Trac allege product deficiencies not related to normal wear; yet, these were not identified as complaints.

   Sunwa's September 30, 1998, response appears to be adequate.

9. Failure of the device history records to include acceptance records which demonstrates that the device is manufactured in accordance with the device master record (DMR), as required by 21 CFR 820.184. For example, the device history records do not contain acceptance records which demonstrate that the following specifications in the device master record, are being met:

   a. The specification for the Stair-Trac rate of climb at 6.5m/min with a 130 kg load, at a 35 degree incline, as shown on drawing QV00-00000000-26-DA1 dated 98.06.16;

   b. The specification for the Stair-Trac rate going downstairs of 7.7 m/min with a 130 kg load, at a 35 degree incline; and

c. The specifications for the Stair-Porter rate of climb at 6m/min, and for the rate going downstairs of 8.6 m/min, both with a load of 130 kg, at a 35 degree angle.

Sunwa's September 30, 1998, response is not adequate. Sunwa developed new specifications for the above by testing a number of each device on a one time basis, because prior device testing showed that the above specifications were not being, and could not be, met. However, the device history records still do not contain acceptance records which demonstrate that the new specifications are being met. This is because Sunwa does not test any finished devices at a 130kg load, on a 35 degree incline, and Sunwa has not demonstrated that its testing of each finished device with 0 kg load, at 0 degrees incline, demonstrates that the above specifications are being met. Further, there was no procedure submitted in Sunwa's response to assure that products not meeting the DMR will not be distributed.

10. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d). For example:

a. The finished device is not tested to ensure the Stair-Trac and Stair-Porter met specifications for rate of upstairs and downstairs at a 130 kg load, on a 35 degree incline;

b. Test data dated Oct. 1996, does not support the upper limit of [redacted] sec/meter ([redacted] m/min) for Stair-Trac upstairs, flat, no load; and

c. There is no test data to support, for the Stair-Porter, acceptance upstairs and downstairs specifications for flat, no load, maximum limit.

This letter is not intended to be an all-inclusive list of deficiencies at your facility and at Sunwa.. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific deviations noted in this letter and in the FDA 483s issued at the close-out of the inspections of the two facilities may be symptomatic of serious underlying problems in your firm's and Sunwa's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violation (Section 501(h)) identified by the Food and Drug Administration (FDA). If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Your firm sent the Center for Devices and Radiological Health (CDRH) a written response on August 10, 1998, stating it believed the observations noted during the inspection of your facility are accurate, and it is committed to rapidly correcting these deficiencies. Your firm committed to these corrections by the end of October 1998. CDRH has not received any specific corrective actions from your firm to date.

Once we receive an adequate response from your firm concerning this letter, a follow-up inspection at your firm will be required to assure that corrections are adequate.

Until it has been determined that corrections are adequate, Federal Agencies are advised of the issuance of all Warning letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these and any other manufacturing or quality systems deviations identified by your internal audit. Given the serious nature of this violation of the Act, all three devices manufactured by your firm may be detained without physical examination upon entry into the United States.

As soon as (1) we receive an adequate response from your firm, (2) the follow-up inspection has taken place, (3) the implementation of your corrections have been verified, and (4) your firm is notified that your corrections are adequate, your firm will be notified that your devices may resume entry into this country.

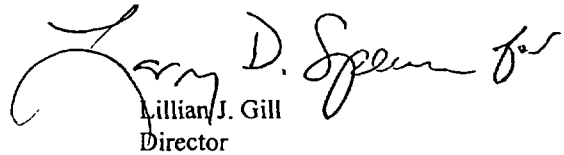
Please notify this office, in writing, within 15 days of receipt of this letter of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that a similar violation will not recur. Please include any and all documentation to show that adequate correction had been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review. Please address your response to:

Mr. William F. Defibaugh
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance, HFZ-343
2098 Gaither Road
Rockville, MD 20850

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains to the issue of the QS regulation, and does not necessarily address other obligations your firm may have under the law. Your firm may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2042 or through the Internet at "**www.fda.gov/cdrh/dsma/dsmamain.html**".

If you have any specific questions about this letter, you may contact Mr. Defibaugh at (301) 594-4660, ext. 121.

Sincerely yours,



Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: Mr. Rintaro Misawa
President
Sunwa, Ltd.